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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/09/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,576

Applicant(s)

BLAKE, LARRY W. 

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40, 42-45, 48-72, 74, 75 and 77-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-39 and 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40, 48-53, 56-59, 61, 67, 68, 74, 75 and 77-79 is/are rejected.
- 7) ☒ Claim(s) 54, 55, 60, 62-66 and 69-72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claims 41, 46, 47, 73, and 76 in Paper No. 8 is acknowledged.
2. Since the application contains cancelled claims, amended claims, and newly added claims, Examiner respectfully requests that the Applicant submits a clean copy of all pending claims to replace those currently filed.

Drawings

3. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

4. The (amended) abstract of the disclosure is objected to because:
 - a. Last two lines of the amended abstract gives the impression that the haptic is attachable to itself by way of cleats ("The haptic is a high modulus skeletal frame, and may be assembled with lower modulus material and is attachable to cleats on the frame."). Correction is required. See MPEP § 608.01(b).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application (see 37 CFR 1.130(b)).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 40, 48-52, 56-59, 61, 67, 74, and 75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-7, 16, 17, 19, 20, 22-24, 26, 27, and 36 of copending Application No. 10/056,971. Although the conflicting claims are not identical, they are not patentably distinct from each other since the referenced copending application and the instant application are claiming common subject matter, as follows: an attachment for a two-part (optic + haptic) IOL comprising a cleat(s) and an eyelet(s).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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8. Claims 77 and 78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kelman (US 4,608,049 A; cited in Applicant's IDS). As seen in Figures 7 and 8, Kelman discloses an attachment for a two-part IOL comprising a cleat(s) on one part of said IOL (see Figure 8; character 81) and an eyelet (see Figure 7; character 76) allowing said cleat(s) to firmly attach on said second part of said two-part IOL (see column 5, lines 19-22; column 6, lines 43-50; column 7, lines 34-60; see entire document).

9. Claims 77 and 78 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kelman (EP 1 138 282 A1). As seen in Figures 1-4, Kelman discloses an attachment for a two-part IOL comprising an optic (deformable lens optic 12), a substantially rigid haptic, a cleat (tab 16) on the lens, and an eyelet (slot or recess 32) on the haptic allowing said cleat to firmly attach to the haptic (see column 5, lines 29-32 and lines 47-54; column 6, lines 5-12 and lines 32-34; see entire document).

Although Kelman does not disclose an incision of 2.5 mm or less, he discloses "*to minimize trauma and the possibility of injury to the eye, the damaged natural lens is typically removed from the eye through a small incision located in the wall of the cornea. It is through this incision that the replacement lens will be inserted, positioned, and secured within the anterior or posterior chamber of the eye.*" (see column 1, lines 40-45). Furthermore, Kelman also discloses "*it would be desirable to provide a two-piece minimum size intraocular lens for easy implantation into and assembly in an eye, following removal of the natural lens. Ideally, the lens components could be inserted into the eye using the same minimum size corneal incision used to remove the natural lens.*" (see column 3, lines 34-39). Therefore, in view of the teachings of Kelman, it would have been obvious to a person of ordinary skill in the art at the time the

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invention was made to have a two-part IOL configured to pass completely through a 2.5 mm or less opening in order to obtain an easy implantation into and assembly in an eye, following removal of the natural lens.

10. Claims 40, 48-53, 67, 68, and 79 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hanna (FR 2 784 575 A1; cited in Applicant's IDS). As seen in Figures 1-5, Hanna clearly discloses the claimed attachment for a two-part IOL (see also entire document).

Response to Arguments

11. Regarding 102(b) rejection over Kelman (US 4,608,04), Applicant's arguments filed January 17, 2003 have been fully considered but they are not persuasive. Applicant argues, "Kelman '049 does not teach or suggest that the IOL can pass through a 2.5 mm or less opening." Examiner respectfully disagrees.

Kelman discloses the optic portion as made of a foldable material (see column 6, lines 43-49). Kelman also discloses "*to insert the lens 70 into the eye through an opening in the cornea, the lens body 71 may be folded over as represented in Fig. 5 or folded in a curl as represented in Fig. 6 to a width of, for example, 3 mm or less.*" (see column 6, lines 61-64). He further discloses, "*the curled dimension of the lens body will control the minimum size of the incision required.*" (see column 6, lines 66-68). This show that the Kelman teach and suggest that the IOL can pass through a 2.5 mm or less opening. Also, it is inherent that since the optic part is (i) foldable, (ii) made of the same materials as in Applicant's IOL, and (iii) intended to be inserted folded through a small incision, it could be folded two or three times in order to fit through a 2.5 mm or less opening.

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12. Regarding 102(e) rejection over Hanna (FR 2 784 575 A1), Applicant's arguments filed January 17, 2003 have been fully considered but they are not persuasive. Applicant argues, "It is physically improbable for the IOL as described in Hanna to be inserted through a 2.5 mm or less opening." Examiner respectfully disagrees.

Although Hanna discloses optical part 6 as been "on the order of seven millimeters", he/she also discloses both annular part 1 and optical part 6 as made of a well-known flexible and pliable material such as acrylic polymer or having a silicone base" (see page 7, lines 22-24). Furthermore, he/she also teaches that the optical part 6 "can also be inserted folded through a small corneal incision" (see page 4, lines 2-5). It is inherent that since the optic part is (i) flexible/pliable, (ii) made of the same materials as in Applicant's IOL, and (iii) intended to be inserted folded through a small incision, it could be folded two or three times in order to fit through a 2.5 mm or less opening.

Allowable Subject Matter

13. Claims 54, 55, 60, 62-66, 69-72, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Parekh (US 5,141,507), Morgan et al. (US 2002/0022882 A1), Brady et al. (US

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2002/0045938 A1), Rochels (DE 3626869 A1), Guillaume et al. (FR 2 728 459 A1), Blake et al. (WO 02/060346 A2).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00 a.m.-4:30 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



JGB

April 5, 2003



David H. Willse
Primary Examiner